REMARKS

1. Disposition of Claims

Claims 20, 22, and 23 are pending in this application. With regard to Claims 20 and 23, these claims have been amended back to original Claims 20 and 23, as has Claim 22 in the sense that it depends from Claim 20. Continuing with Claim 22, it nevertheless differs from original Claim 22 in that the term "bacteria" was previously determined to lack exact antecedent basis and thus the claim was previously amended to provide the term "bacteriophage" having exact antecedent basis and to connect up these terms with each other. No new matter has been added. Reexamination and reconsideration of the application, as amended, are respectfully requested.

2. Compliance with 35 USC 112/1 - Enablement

In the next-to-last Office Action, mailed November 20, 2006, the Patent Office maintained the rejection of the claims under 35 USC 112/1 as failing to meet the enablement requirement on the reasoning that there is no teaching in the specification nor in subsequent non-patent literature that the claimed genetic engineering method was ever attempted or if attempted was ever successful in producing phages that are capable of evading a host defense system (HDS). The rejection was respectfully traversed. The priority date of this application was reiterated to be April 5, 1994.

Applicant remarked that: The invention solves the problem in the prior art of the use of bacteriophage to fight infections caused by bacteria. One explanation for bacteriophage not always working was because the viruses were inactivated by the host defense system. To solve this problem, the inventors developed a technology to produce bacteriophage that may be serially passaged or genetically modified to delay inactivation by the host defense system.

Applicant remarked that: Using the serial passage technology, the inventors developed long-circulating bacteriophage that are greatly superior to wild-types in terms of rescuing animals from otherwise fatal infections. These results were published as the post-filing date inventor-created art of Merril et al., Proc Natl Acad Sci USA 93: 3188 (1996) of record.

Applicant remarked that: Using the genetic engineering technique, the inventors proceeded to demonstrate that the mutation in the major phage capsid (E) protein, which resulted in the change of the acidic amino acid glutamate to the basic amino acid lysine at residue 158, conferred the "long-circulating" phenotype. The inventors identified the mutation and then

incorporated this mutation into a wild-type background. These results were published as the post-filing date inventor-created art of Vitiello et al., Virus Res 114: 101 (2005), of record.

Applicant remarked that: Regarding the paragraph bridging page 3 and 4 of the Office Action about a further step of genetically engineering a bacteriophage to express a peptide on its surface coat that delays inactivation of the bacteriophage by an animal's host defense system, wherein the peptide inhibits complement activation, this further step is not antithetical to patentability, because routine experimentation can be required without violating the enablement requirement.

Applicant remarked that: In short, the inventors were able to duplicate the solution to the host defense problem afforded by the serial passage technique with the genetic engineering technology. Therefore, not only is there is a teaching in the specification, which is prophetic, but also there is a teaching in subsequent non-patent scientific literature demonstrating that the claimed genetic engineering method, besides being attempted, was actually successful in producing phages that are capable of evading a host defense system (HDS).

In the last Office Action, mailed March 21, 2007, the Patent Office maintained the rejection of the claims under 35 USC 112/1 as failing to meet the enablement requirement on the reasoning that that there is no teaching in the specification nor in subsequent non-patent literature that the claimed genetic engineering method was ever attempted or if attempted was ever successful in producing phages that are capable of evading a host defense system (HDS) by inhibiting complement activation. This is so, posited the Patent Office, despite the availability of methods for testing complement activation, citing Kirschfink, M. and Mollnes, TJ.E. Clin Diagn Lab Immunol. 10:982, 2003. Thus, this limitation has been struck from the claims.

There is a teaching in the specification, which is prophetic, and in subsequent non-patent literature that the claimed genetic engineering method was attempted and was successful in producing phages that are capable of evading a host defense system (HDS), as remarked before and presently reiterated below.

Specification: The Patent Office takes the position that the disclosure teaches several strategies for genetic engineering: 1) Mutanogenesis of bacteriophage by chemical or radiant means (see p 11, lines 11-24); 2) expression of specific complement-antagonistic peptide on the surface of the bacteriophage as a fusion protein with bacteriophage surface proteins (see p 12,

line 22-p 13, line 12); 3) expression of known human complement-antagonistic protein on the surface of the bacteriophage in lieu of or in addition to bacteriophage proteins (see p 13, lines 15-25); 4) genetic engineering of other proteins to escape the HDS, e.g., interleukins, cytokines, etc. (see p 14, lines 3-10); and 5) obtaining glycosylated proteins expressed on the surface of the bacteriophage (see p 14, lines 11-19). In addition, referring to p. 12, lines 1-5, another strategy for genetic engineering taught by the disclosure is to genetically engineer a phage so that it expresses molecules on its surface coat, where said molecules antagonize, inactivate, or in some other manner impede those actions of the HDS that would otherwise reduce the viability of the administered phage.

Exemplification: According to MPEP 608.01(p), prophetic examples (paper examples) are permitted in patent applications, where paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted. Example 4 is such a prophetic example. Example 4 describes the manner and process of genetic engineering of phage to express molecules that antagonize the host defense system, thereby enabling the phage to delay inactivation by the host defense system.

Subsequent scientific literature: The rule according to MPEP 2164.05 is that an applicant may provide a declaration after the filing date that demonstrates that the claimed invention works as claimed. Referring to Declaration under 37 CFR 1.132 of Carl R. Merril, M.D. ¶ 5, of record, the post-filing date art Vitiello et al. 2005, supra, is such a demonstration. The post-filing date art Vitiello et al. 2005, supra, demonstrates genetic engineering of phage to express molecules that antagonize the host defense system, thereby enabling the phage to delay inactivation by the host defense system, thus, besides working the invention of Example 4, establishing that the claimed invention works as claimed.

In conclusion, because there is a teaching in the specification, which is prophetic, and there is also a teaching in subsequent non-patent scientific literature demonstrating that the claimed genetic engineering method, besides being attempted, was actually successful in producing phages that are capable of evading a host defense system (HDS), the Patent Office cannot properly maintain the rejection of the claims (amended back to the original claims) under 35 USC 112/1 as failing to meet the enablement requirement.

CONCLUSION

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 6/21/07

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AMEND

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